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Sanofi Pasteur Inc. Intellectual Property - Knerr Building One Discovery Drive Swiftwater, PA 18370				
			EXAMINER	
			DEVI, SARVAMANGALA J N	
			ART UNIT	PAPER NUMBER
			1645	
			MAIL DATE	DELIVERY MODE
			09/28/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/031,165

Applicant(s)

LOOSMORE ET AL.

Examiner

S. Devi, Ph.D.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-11 and 21-24 ~~is/are~~ pending in the application.
- 4a) Of the above claim(s) 1, 2, 4, 7, 8 and 21-24 ~~is/are~~ withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3, 5, 6 and 9-11 ~~is/are~~ rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01/17/02 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 112702
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### **Preliminary Amendments**

- 1) Acknowledgment is made of Applicants' preliminary amendments filed 01/17/02, 03/08/06, 11/29/06 and 06/22/07.

### **Election**

- 2) Acknowledgment is made of Applicants' election filed 03/08/06 in response to the restriction requirement mailed 12/07/05. Applicant have elected of invention I, claims 1-11, and the nucleic acid species encoding SEQ ID NO: 48. Because Applicants did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (M.P.E.P § 818.03(a)).

### **Status of Claims**

- 3) Claims 12-20 have been canceled via the amendment filed 03/08/06.  
Claims 1-11 and 21-24 are pending.  
Claims 1, 2, 4, 7, 8 and 21-24 have been withdrawn from consideration as being directed to a non-elected invention or species. See 37 C.F.R 1.142(b) and M.P.E.P § 821.03.  
Claims 3, 5, 6 and 9-11 are under examination.

### **Information Disclosure Statement**

- 4) Acknowledgment is made of Applicants' Information Disclosure Statement filed 11/27/02. The information referred to therein has been considered and a signed copy is attached to this Office Action.

### **Sequence Listing**

- 5) Acknowledgment is made of Applicants' CRF and the raw sequence listing which have been entered 07/12/07.

### **Priority**

- 6) The instant application is a national phase application filed under 35 U.S.C § 371 of the international application PCT/CA00/00870, filed 07/26/2000, which is a continuation-in-part of application 09/361,619 filed 07/27/1999, *now abandoned*.

## Specification

7) The specification is objected to for the following reason(s):

(a) The amendment made to the first paragraph of the specification via the amendment filed 01/17/02 does not include the current status and filing information of the earlier application SN 09/361,619 as indicated above under the section 'Priority'.

(b) The amendment to pages 10 and 40 the specification requested via the preliminary amendment filed 01/17/02 is non-compliant under 37 C.F.R 1.121. The amendment lacks proper markings as required.

Note that 37 CFR 1.121 (1) (ii) requires that amendment to replace a paragraph must be made by submitting: (i) An instruction, which unambiguously identifies the location, to replace a paragraph with one or more replacement paragraphs; and (ii) The full text of any replacement paragraph 'with markings' to show all the changes relative to the previous version of the paragraph. The text of any added subject matter must be shown by underlining of the added text. The text of any deleted matter must be shown by strike-through except that double brackets placed before and after the deleted characters may be used to show deletion of five or fewer consecutive characters. The text of any deleted subject matter must be shown by placing within double brackets, if strikethrough cannot be easily perceived.

(c) The amino acid sequence 'VVAGK' recited at line 26 of page 39 of the specification is longer than four amino acids in length. Yet the sequence is not identified by specific SEQ ID number as required under 37 C.F.R 1.821 through 1.825. Any sequences recited in the instant specification, which are encompassed by the definitions for nucleotide and/or amino acid sequences as set forth in 37 C.F.R. 1.821(a)(1) and (a)(2) must comply with the requirements of 37 C.F.R 1.821 through 1.825. Note that branched sequences are specifically excluded from this definition.

APPLICANT MUST COMPLY WITH THE SEQUENCE RULES WITHIN THE SAME TIME PERIOD AS IS GIVEN FOR RESPONSE TO THIS ACTION, 37 C.F.R 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 C.F.R 1.821(g).

(d) The specification and the raw sequence listing are confusing in the identification of the same sequence VVAGK by two different sequence identifiers, i.e., SEQ ID NO: 40 at lines 23

and 24 of page 39; and SEQ ID NO: 51 at line 3 of page 40. It is suggested that Applicants use one sequence identifier to identify each sequence.

### **Rejection(s) under 35 U.S.C. § 112, First Paragraph**

8) Claims 3 and 9 are rejected under 35 U.S.C. § 112, first paragraph, as failing to provide an enabling disclosure, because the specification does not provide evidence that the claimed biological material is (1) known and readily available to the public; (2) reproducible from the written description, e.g. sequenced; or (3) deposited.

Claims 3 and 9 include the limitation: "pBR T7 3' 200 kDa(t)/*KanR/Cer*" plasmid vector, or a plasmid vector having the identifying characteristics of the pBR T7 3' 200 kDa(t)/*KanR/Cer* respectively. It is apparent that the claimed vectors are required to practice the claimed invention. The vector claimed in claim 9 encompasses one that has selective identifying characteristics of the pKS348 (ATCC 203529) or partial identifying characteristics of the pBR T7 3' 200 kDa(t)/*KanR/Cer*. As required elements, the vectors must be known and be readily available to the public, or obtainable by a reproducible method set forth in the specification, or otherwise be readily available to the public. If not so obtainable or available, the enablement requirements of 35 U.S.C. § 112, first paragraph, may be satisfied by a deposit of the claimed vectors. From page 21 of the specification, it appears that pBR T7 3' 200 kDa(t)/*KanR/Cer* plasmid vector, or a plasmid vector having the identifying characteristics of the pBR T7 3' 200 kDa(t)/*KanR/Cer* pKS348, is not deposited at an acceptable depository. To comply with the deposit practice, filing of an affidavit or declaration by Applicants or assignees, or a statement by an attorney of record who has authority and control over the conditions of the deposits over his or her signature and registration number stating that the deposits have been accepted by an International Depository Authority under the provisions of the Budapest Treaty, that all restrictions upon public access to the deposits will be *irrevocably* removed upon the grant of a patent on this application, is required. This requirement is necessary when the deposits are made under the provisions of the Budapest Treaty as the Treaty leaves this specific matter to the discretion of each state. Further, the statement should identify the deposited vectors by their depository accession number, establish that the deposited products are the same as the one described in the specification, and establish that the deposited products were in

Applicants' possession at the time of filing. As a means of satisfying the necessary criteria of the deposit rules and to show that the vectors deposited are the same as the ones deposited with the specific identification numbers, Applicants may submit a copy of the contract or a notice of acceptance of the vectors by the depository.

Applicants' attention is directed to *In re Lundack*, 773 F.2d. 1216, 227 USPQ 90 (CAFC 1985) and 37 C.F.R § 1.801-1.809 for further information concerning deposit practice.

### **Rejection(s) under 35 U.S.C § 112, Second Paragraph**

9) The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his/her invention.

10) Claims 3, 5, 6 and 9-10 are rejected under 35 U.S.C § 112, second paragraph, as being indefinite, for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claim 3 is vague and indefinite in the limitation 'derived', because it is unclear what is encompassed in this recitation. Does the process of 'deriving' encompass extraction, isolation, recombinant production, separation, purification, modification, amino acid substitution, or expression on cell surface?

(b) Claim 3 is indefinite in the recitation 'set forth in Figure 21', because it fails to point out what is included or excluded by the claim language. M.P.E.P 2173.05(s) states that where possible, claims are to be complete in themselves. Incorporation by reference to Tables, and Figures, or Examples as in this case, is a necessity doctrine, not for Applicants' convenience. See *Ex parte Fressola*, 27 USPQ2d 1608, 1609 (Bd. Pat. App. & Inter. 1993).

(c) Analogous rejection and criticism apply to claim 9 with regard to the limitation 'Figure 23'.

(d) Claim 3 is vague and indefinite in the limitation: 'a nucleotide sequence ..... for a N-terminal and C-terminal truncation of an about 200 kDa outer membrane protein of *Moraxella catarrhalis* strain 4223 produced by pBR T7 3' 200 kDa(t)/*KanR/cer*'. Does it mean that the recited nucleotide sequence represents a full length gene encoding an about 200 kDa outer membrane protein

as recited and is meant for further N-terminal and C-terminal truncation to be produced by pBR T7 3' 200 kDa(t)/*KanR/cer*', or is it already an N-terminally and C-terminally truncated nucleotide sequence produced by pBR T7 3' 200 kDa(t)/*KanR/cer*? Clarification is requested.

(e) Claim 5 lacks proper antecedent basis in the limitation: 'a nucleic acid molecule as claimed in ....'. For proper antecedent basis, it is suggested that Applicants replace the above-identified limitation with the limitation --the nucleic acid molecule as claimed in ...--.

(f) Claim 9 appears to lack proper antecedent basis in the limitation "pBR T7 3' 200 kDa(t)/*KanR/cer*". Claim 9 depends indirectly from claim 3 which already includes the limitation. Does it mean that "pBR T7 3' 200 kDa(t)/*KanR/cer*" recited in dependent claim 9 is different from the one that is recited in claim 3?

(g) Claim 10 lacks proper antecedent basis in the limitation: 'a vector as claimed in claim 5'. For proper antecedent basis, it is suggested that Applicants replace the above-identified limitation with the limitation --the vector as claimed in claim 5--.

(h) Claims 5, 6 and 9-11, which depend directly or indirectly from claim 3, are also rejected as being indefinite because of the indefiniteness or vagueness identified above in the base claim.

### **Rejection(s) under 35 U.S.C § 102**

**11)** The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**12)** Claims 3, 5, 6 and 9-11 are rejected under 35 U.S.C § 102(b) as being anticipated by Sasaki *et al.* (WO 96/34960 - Applicants' IDS). ('960).

The limitation 'for a N-terminal and C-terminal truncation of an about 200 kDa outer membrane protein of *Moraxella catarrhalis* strain 4223 produced by pBR T7 3' 200 kDa(t)/*KanR/Cer*' is viewed as representing the intended use of the claimed nucleic acid molecule.

Sasaki *et al.* ('960) disclosed an isolated and purified nucleic acid molecule having a nucleotide sequence encoding a 200 kD outer membrane protein of the 4223 strain of *M.*

*catarrhalis*. Sasaki's ('960) nucleic acid molecule comprises a nucleotide sequence as depicted in Figure 6 which contains nucleotide bases 3550 to 5997 that are identical in structure to nucleotide bases 1-816 of the instantly recited SEQ ID NO: 48. A plasmid or an expression vector for transforming a host comprising the nucleic acid molecule is taught wherein the host cell is *E. coli*. See abstract; claims 14-23; paragraph 1 of page 4; Figure 6; page 28; and claims 14-23.

Claims 3, 5, 6 and 9-11 are anticipated by Sasaki *et al.* ('960).

### Remarks

- 13) Claims 3, 5, 6 and 9-11 stand rejected.
- 14) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. The Fax number for submission of amendments, responses and/or papers is (571) 273-8300, which receives transmissions 24 hours a day and 7 days a week.
- 15) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (in USA or CANADA) or 571-272-1000.
- 16) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Jeffrey Siew, can be reached on (571) 272-0787.

September, 2007

  
S. DEVI, PH.D.  
PRIMARY EXAMINER